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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/013,077	01/26/98	NAUSS	J

HM22/0104

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EXAMINER	
WESSENDORF, T	
ART UNIT	**PAPER NUMBER**
1627	19

DATE MAILED: 01/04/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applic
09/013,077	Naus t al
Examiner	Group Art Unit
T. W ss ndorf	1627

☒ Responsive to communication(s) filed on *10/19/00*

☒ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) *15-47* is/are pending in the applicat

Of the above, claim(s) *38-47* is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *15-37* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). *17*

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Upon careful consideration of the species restriction and applicants' amendments to the claims, the restriction with respect to the species is withdrawn. However, newly presented claims 38-47 are withdrawn from consideration as being drawn to the non-elected invention. See Papers Nos. 6 and 10.

Claims 15-37 are under consideration. Contrary to applicants' arguments claims 1-14 drawn to the non-elected peptide has been included in the present amendments as claims 38-42. [Note claims 43-47 improperly depends and recites vaccines instead of peptides].

The oath or declaration is defective. A new oath or declaration in compliance with 37 CAR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

Inventor Scheherazade has not provided an oath or declaration.

It is argued that a Petition has been submitted under 37CRF 1.47 since this inventor cannot be successfully located. However, in the absence of said signed declaration, the objection to the declaration as being defective is maintained.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 15-37 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention for reasons advanced in the last Office action.

It is argued that it is well accepted in the art that if a peptide binds to the DR1 binding assay, it is immunogenic in humans. However, immunogenicity is not the same as vaccine effect which includes not only treatment but prevention of a certain disease, especially neoplasms, as claimed. Furthermore, there is nothing of record to support applicants' arguments. And mere arguments and general statements in the specification as to the effectiveness of the vaccine composition would not suffice as a written description of the invention. It is not apparent from the minimized peptide models whether the models have been predictive of vaccine effect since no vaccine has been made or tested to

show such vaccine effect of the model to the intended host. As a skilled would appreciate, the generation of an immune response, or neutralizing response in particular, cannot be equated with preparation of a protective vaccine. A vaccine is administered for the prevention, amelioration or treatment of infections disease (neoplasms and pathogenic microorganism in the instant case). Thus, there is no indication that this model has been successfully employed as a vaccine. Applicants argue that a synthetic peptide wherein the amino acid of the minimized peptide has been modified can easily be obtained by one of ordinary skill in the art of molecular modeling and computation chemistry using a computer to modify and test the synthetic peptide in the model for binding ability. Tables I and II is alleged to show a minimized peptide HA and a synthetic peptide HA-YK and the amino acid sequences therefore. The minimized peptide and the synthetic peptides are argued to be similar except for the possibility of amino acid substitution. Although a computer can be used however, no matter how sophisticated said computer modeling still it cannot mimic the actual effect in the real environment where compound solubility, interactions or non-interactions and other factors are present in an unpredictable effect. Furthermore, as admitted by applicants, synthetic peptides are different from the

natural ones and therefore, the unpredictable effect of the modifications cannot be predicated from the natural or native one.

The recitation of a vaccine against pathogenic microorganism and neoplasms are not supported in the as-filed specification. The specification does not recite for any kind of neoplasms. The specific microorganisms e.g., E.Coli recited in the original disclosure would not provide support for the now broadly recited microorganisms. E.g., claim 22.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 15-37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A). Claim 15 is unclear whether the peptide is effective as a vaccine since the claim merely recites that the peptide is "capable of binding to a class II MHC receptor DRI and inhibiting the binding of HA residues 306-381".

B). Claim 16 broadens the base claim which does not recite for a modified peptide. The term "superior" is a relative term and therefore indefinite. The language "when said synthetic peptide is minimized" connotes uncertainty and unclear whether said synthetic peptide is in fact minimized which is therefore inconsistent with the base claim minimized peptide.

C). Claim 17 is a duplicate of claim 16 since the same, exact limitation is recited therein, except the function of binding and inhibiting is merely reversed.

D). Claim 23 recitation of "at least a portion of said synthetic peptide" is unclear since it is not clear as to what constitutes a portion of an already minimized peptide.

E). "Incapsulation" is misspelled as recited in claims 25-30.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 15-37 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Reid (Jrnl. Of Immunology, April 15, 1993) for reasons of record.

It is argued that the reference predates the present invention by one month. However, the present invention is a CIP of the parent application and of different authors than the present inventors.

Claims 15-20 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over anyone of Jackson (Peptide Research) or Busch et al (Jrnl. Of Immunology) or Tang et al (Jrnl. Of Virology) or

Rothbard (Bacterial Toxins) or Romagnoli et al (Infec. Res. Immunol.).

Each of these references discloses a composition which contains a minimized peptide that inhibits binding of the HA to the MHC receptor DRI or obviously inhibits said binding since MHC is known to be the receptor for HA. Therefore, each of these references anticipates or renders obvious the claim to a composition containing broadly a minimized peptide as the main component since each of these references discloses a specific minimized peptide.

Claims 15-37 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Reid et al (5,417,986)(102e).

Reid discloses a composition which contains a minimized peptide. It is considered that the recited function of the minimized peptide is inherent to the peptide of Reid. Therefore, the Reid reference anticipates or renders obvious the claim to a composition containing broadly a minimized peptide as the main component since Reid discloses a specific minimized peptide.

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CAR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CAR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

This application contains claims 18-20 and 38-47 drawn to a nonelected invention. A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Certain papers related to this application may be submitted to Art Unit 1627 by facsimile transmission. The faxing of such

papers must conform with the notices published in the Official Gazette, 1156 O.G. 61 (November 16, 1993) and 1157 O.G. 94 (December 28, 1993)(see 37 C.F.R. 1.6(d)). The official fax telephone numbers of the Group are (703)308-7924. NOTE: If applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. Wessendorf whose telephone number is (703) 308-3967. The examiner can normally be reached on Mon. to Fri. from 8 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jyothsna Venkat Ph.D., can be reached on (703) 308-0570. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

T. Wessendorf
Patent Examiner
Art Unit 1627
12/29/00